

11. A respiratory suction apparatus according to Claim 10, wherein the rate of airflow is responsive to application of negative pressure in the catheter.

12. A respiratory suction apparatus according to Claim 11, wherein the rate of airflow is filtered ambient air and the means for providing a predetermined rate of airflow further comprising an opening in the enclosure.

REMARKS

In the Office Action of October 21, 2002, claims 1 and 2 were rejected under 35 U.S.C. §102(b) as being anticipated by Niermann et al. (U.S. Patent No. 5,354,267).

Also in the Office Action, claims 3-7, 10, and 11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Niermann.

Additionally, claim 8 was rejected in the Office Action under 35 U.S.C. §103(a) as being unpatentable over Niermann in view of Reynolds (U.S. Patent No. 5,370,610).

Also, claim 9 was rejected under 35 U.S.C. §103(a) as being unpatentable over Niermann and Reynolds and further in view of Loescher et al. (U.S. Patent No. 5,005,568).

Finally, in the Office Action of October 21, 2002, claim 12

was rejected under 35 U.S.C. §103(a) as being unpatentable over Niermann in view of Reynolds.

Applicants respectfully submit that amended independent claim 1 defines over Niermann. Respectfully, Niermann does not disclose a respiratory suction apparatus that has a cylindrical space defined by a collar and catheter in fluid communication with a lavage port, where the lavage port is in fluid communication with an artificial airway of the patient through the cylindrical space and the adapter. Support for this amendment can be found on at least page 17, lines 9-14 of the specification, and in at least Figures 3A-3E of the drawings and related discussion.

The Office Action of October 21, 2002 indicated on page 2 that Niermann discloses a collar 32 disposed within the adapter. The collar 32 disclosed by Niermann is actually a rotatable disk 32 (see Niermann at column 5, line 13). The disk 32 of Niermann may be moved into three different positions, those being a suction position as disclosed in Figure 1, a flushing or cleaning position as disclosed in Figure 2, and an irrigation or lavage position as shown in Figures 3 and 4 (see Niermann at column 5, lines 52-57, and Figures 1-4). In the suctioning position as shown in Figure 1 of Niermann, the suction catheter 18 is advanced through a passageway 34 that is surrounded by the disk

32 (see Niermann at column 5, lines 9-12; and Figure 1).

In the suctioning position, lavage solution is not capable of being transferred from the irrigation fluid input port 40 to the patient. This is because the irrigation fluid input port 40 is blocked by the disk 32 as can be seen in Figure 1 of Niermann. As such, the irrigation fluid input port 40 is not in fluid communication with a front coupling 14 or the patient's artificial airway.

In order to provide lavage solution to the patient or to clean the suction catheter 18, the suction catheter 18 is retracted from the disk 32 and placed into the positions shown in Figures 2 and 3 of Niermann (see Niermann at column 5, lines 9-12).

In order to provide lavage solution to the patient, the disk 32 is rotated into the position shown in Figure 3 of Niermann (see Niermann at column 5, lines 35- 41). In this position, lavage solution may be directed into the patient through the passageways 34 and 36 of the disk 32 as indicated by the curved arrow 86 in Figure 3 (see Niermann at column 5, lines 35-41). In this position, the catheter 18 and the disk 32 do not define a cylindrical space through which the irrigation fluid input port 40 is in fluid communication with the patient and/or an adapter. In Figure 3 of Niermann, the catheter 18 is completely isolated

from the lavage solution that is directed towards the patient (see Niermann at column 5, lines 46-51; and Figure 3). Niermann therefore discloses a respiratory suction apparatus that has a structure wherein the catheter 18 is not surrounded by the disk 32 to form a cylindrical space through which lavage solution is directed into the coupling or adapter 14 and into the patient.

Amended Claim 1 calls for a structure that is essentially opposite from that disclosed in Niermann. Amended claim 1 calls for a collar and catheter defining a cylindrical space through which a lavage port is in fluid communication with the patient's artificial airway and the adapter. This structure is essentially opposite from Niermann which calls for the catheter to be retracted from the disk and hence not forming a cylindrical space through which irrigation is provided to the patient (see Niermann at column 5, lines 9-12; and Figure 3).

It would not have been obvious for one of ordinary skill in the art to modify the disk 32 so that lavage may be directed towards the patient while the catheter is at least partially surrounded by the disk 32 and forms a cylindrical space. This is because doing so would go completely against the teachings of Niermann which calls for a blockage of fluid to the catheter 18 when fluid is provided to the patient (see Niermann at column 5, lines 46-51; and column 6, lines 38-40 "a passageway for

directing said irrigation fluid solely to the trachea of said patient"). This blocking necessarily prevents the formation of a cylindrical space defined by the catheter 18 and disk 32 through which lavage fluid may be transferred to the patient. As such, Applicants respectfully submit that amended independent claim 1 is patentable over Niermann.

Therefore, Applicants respectfully submit that independent claim 1 is in proper condition for allowance and that all claims which depend directly or indirectly from independent claim 1 are also in condition for allowance (claims 2-9), their rejections being made moot due to the allowance of independent claim 1.

As stated, independent claim 10 was rejected in the Office Action of October 21, 2002, under §103(a) as being unpatentable over Niermann. Applicants have amended claim 10 such that it now calls for a lavage port in fluid communication with a cylindrical space defined by a collar and catheter, where the lavage port is in fluid communication with the patient's artificial airway through the cylindrical space and an adapter. This amendment is similar to the amendment made to claim 1 as discussed above, and Applicants submit that amended claim 10 defines over Niermann for essentially the same reasons as discussed above with respect to independent claim 1.

Therefore, Applicants respectfully submit that independent

claim 10 is in proper condition for allowance and that all claims which depend directly or indirectly from independent claim 10 are also in condition for allowance (claims 11 and 12), their rejections being made moot due to the allowance of independent claim 10.

Applicants respectfully submit that all claims are allowable and the application is in condition for allowance. Favorable action thereon is respectfully requested.

The Examiner is encouraged to call the undersigned at his convenience to resolve any remaining issues.

Respectfully submitted,

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Amended Claims for U.S. Serial No. 09/716,486 Bal-66-CON (BA00118.4)

1. (Twice Amended) A respiratory suction apparatus comprising:
 - a suction catheter for removing fluids from a respiratory tract of a patient by insertion of a distal end of the catheter into said respiratory tract and withdrawal of the distal end of the catheter through a portion of said tract while applying negative pressure to a lumen of the catheter;
 - a protective sleeve surrounding a proximal longitudinal portion of the catheter;
 - a distal adapter configured for communication with a manifold of a patient's artificial airway;
 - a collar disposed within the adapter and partially surrounding the distal end of the catheter when the catheter is withdrawn from the manifold, the collar and the catheter defining a substantially uniform cylindrical space around a distal portion of the catheter, the cylindrical space capable of directing lavage solution into the adapter; [and]
 - a valve device configured in the adapter to substantially isolate the catheter from the manifold upon withdrawing the distal portion of the suction catheter from said manifold and applying suction through the catheter lumen, said valve device being opened by advancement of said suction catheter through said

valve device; and

a lavage port in fluid communication with the cylindrical space defined by the collar and the catheter, the lavage port in fluid communication with the patient's artificial airway through the cylindrical space and the adapter.

10. (Twice Amended) A respiratory suction apparatus comprising:

an elongate suction catheter having a distal end;

a protective sleeve surrounding a proximal portion of the catheter;

a distal adapter configured for communication with a manifold of a patient's artificial airway;

a collar disposed within the adapter and partially surrounding the distal end of the catheter when the catheter is withdrawn from said manifold, the collar and the catheter defining a substantially uniform cylindrical space around a distal portion of the catheter, the cylindrical space capable of directing lavage solution into the adapter;

a cleaning enclosure defined within the adapter wherein the distal end of the catheter is exposed to cleaning liquids and turbulent airflow during a cleaning procedure;

means for providing a predetermined rate of airflow to the enclosure responsive to negative pressure within the catheter;

the catheter being protected at all serviceable times

against environmental contamination by a combination of the sleeve, adapter and enclosure; [and]

a valve device, comprising a flap and a hinge, configured in the adapter whereby the flap occludes the catheter responsive to a pressure differential between said manifold and the enclosure, the catheter opens the flap by manual insertion pressure of the catheter on the flap, and the hinge retains the flap; and

a lavage port in fluid communication with the cylindrical space defined by the collar and the catheter, the lavage port in fluid communication with the patient's artificial airway through the cylindrical space and the adapter.